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No. _____

In the Supreme Court of the United States

L. PERRIGO COMPANY and PERRIGO COMPANY,
Petitioners,

v.

MCNEIL-PPC, INC.,
Respondent.

On Petition for Writ of Certiorari To The United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

JAMES A. MITCHELL
Counsel of Record

PRICE, HENEVELD, COOPER, DEWITT & LITTON
695 KENMOOR, S.E.
POST OFFICE BOX 2567
GRAND RAPIDS, MI 49501
(616) 949-9610

Counsel for Petitioners

BECKER GALLAGHER LEGAL PUBLISHING, INC.,
CINCINNATI, OHIO 800-890-5001

QUESTIONS PRESENTED

This is one of two petitions filed contemporaneously in different cases seeking review of unconstitutional legislative action by the United States Court of Appeals for the Federal Circuit in effectively amending section 285 of Title 35 of the United States Code.

35 USC §285 gives a trial judge the authority in patent cases to award reasonable attorney fees to the prevailing party in "exceptional cases." The United States District Court for the Eastern District of Pennsylvania awarded attorney fees to Petitioners in this case, finding as fact that:

> "Particularly during the prosecution of the [Garwin] patents in suit, McNeil's conduct was careless, irresponsible, and at the very least, tantamount to studied and deceptive ignorance. . . . Although McNeil's misconduct during prosecution alone makes this case exceptional, there is further evidence warranting an award of attorneys' fees." (59a)

The Court of Appeals for the Federal Circuit affirmed the District Court's findings of patent invalidity and noninfringement, but reversed the award of attorney fees on the grounds that in order to be an "exceptional case" under 35 USC §285, there must be a finding of:

> inequitable conduct before the PTO;
> misconduct during litigation, vexatious or unjustified litigation, and frivolous suit; or
> willful infringement (17a, 18a).

The questions presented in this Petition are:

1. Whether the Federal Circuit Court has unconstitutionally limited the discretion given by Congress to trial judges to award attorney fees in exceptional cases, by in effect amending 35 USC §285 to restrict the definition of "exceptional case" to those cases falling into one of three specific boxes?

2. Whether a District Court's discretion is not abused in finding a case to be exceptional based on conduct which was careless, irresponsible, and at the very least, tantamount to studied and deceptive ignorance?

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner L. Perrigo Company is a wholly owned subsidiary of Petitioner Perrigo Company. There are no publicly held companies that own 10% or more of the corporate stock of Perrigo Company.

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OPINIONS AND ORDERS BELOW

The opinion of the United States District Court for the Eastern District of Pennsylvania (21a-64a) is reported at 207 Fed. Supp.2d 356 (E.D. Pa 2002). The opinion of the Court of Appeals for the Federal Circuit (1a-20a) is reported at 337 F.3d 1362 (Fed. Cir. 2003).

JURISDICTION

The judgment of the Federal Circuit was entered on August 1, 2003. The jurisdiction of this Court is invoked under 28 USC 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND FEDERAL REGULATIONS

Article I, Section 8 of the Constitution of the United States provides in pertinent part:

> The Congress shall have power . . . to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries; . . . and
>
> To make all laws which shall be necessary and proper for carrying into execution the foregoing powers, and all other powers vested by this Constitution in the Government of the United States, or any department or officer thereof.

Section 285 of the Patent Laws of the United States, Title 35, provides:

Attorney Fees: The court in exceptional cases may award reasonable attorney fees to the prevailing party.

United States Patent Office Rule 37 CFR §1.56 provides in pertinent part:

> (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. . . . The Office encourages applicants to carefully examine:
>
> > . . .(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
>
> (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> > (1) It establishes by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

i) opposing an argument of unpatentability relied on by the Office, or
ii) asserting an argument of patentability.

STATEMENT OF THE CASE

The District Court Decision

This being a case brought under the Patent Laws of the United States, the jurisdiction of the District Court is authorized under 28 USC §1338, and the jurisdiction of the United States Court of Appeals for the Federal Circuit is authorized under 28 USC §1295.

On March 7, 2001, McNeil filed suit against Petitioners Perrigo and L. Perrigo under 35 USC §271(e)(2)(A), alleging that L. Perrigo's submission of its ANDA (abbreviated new drug application) to make a generic, store brand alternative to McNeil's Imodium Advanced product, was an act of infringement of numerous claims of Garwin Patents 5,248,505 and 5,612,054 to compositions containing loperamide anti-diarrheal and simethicone anti-flatulent ingredients, and Stevens Patents 5,716,641 and 5,679,376 to loperamide and simethicone combination tablets having a simethicone oil impermeable polymeric barrier between the simethicone and the loperamide containing portions of the tablet. (4a-7a) On June 25, 2002, the United States District Court for the Eastern District of Pennsylvania entered judgment finding all four patents invalid, finding the Stevens patents not infringed, and awarding attorney fees to Petitioners. The Court specifically found that:

"Particularly during the prosecution of the [Garwin] patents in suit, McNeil's conduct was careless, irresponsible, and at the very least, tantamount to studied and deceptive ignorance. . . . Although McNeil's misconduct during prosecution alone makes this case exceptional, there is further evidence warranting an award of attorneys' fees." (59a)

Material False Representations and Omissions in Prosecution Of The Garwin Patents

The evidence submitted at trial amply supports the District Court's finding that McNeil's conduct during prosecution of the Garwin patents in suit was "careless, irresponsible, and at the very least, tantamount to studied and deceptive ignorance." When the basic loperamide Patent, 3,714,159, was about to expire, McNeil asked Dr. Garwin "to think more aggressively about patents." (26a) These instructions led Garwin to file two patent applications to compositions combining simethicone anti-flatulent with loperamide anti-diarrheal, and the use of that combination in treating diarrhea and associated gas.

McNeil was aggressive to the point of carelessness in prosecuting the Garwin patents. McNeil made six separate material false representations and omissions, as well as material omissions related to some of the false representations, to the United States Patent Office over the course of 7½ years of patent prosecution:

1. **Contrary to fact**, McNeil repeatedly asserted during prosecution of the first Garwin patent ('505) that Garwin was the first to discover that people with diarrhea also have gas, i.e. that diarrhea and flatulence are concurrent symptoms.

While the Longe prior art reference of record in the Patent Office included a statement refuting this assertion, McNeil obfuscated the teaching of this reference by specifically stating that:

> This reference identifies and discloses anti-diarrheal compositions but ***nowhere does it disclose or recognize the problem of flatulence or gas associated with diarrhea*** nor provide for a combination of an anti-diarrheal and anti-gas composition. (Emphasis added.)

2. **Contrary to fact**, it was repeatedly asserted, both during the '505 and '054 prosecution, that Garwin was the first to combine an anti-diarrheal with simethicone, and significantly the Examiner gave this as his "Reasons for Allowance" of the second Garwin patent ('054). McNeil's attorney declined the Examiner's invitation to comment on the "Reasons for Allowance," and correct the Examiner's misunderstanding of the record, even though McNeil **knew** by then that its earlier representations about Garwin being the first to combine an anti-diarrheal with simethicone were false.

3. **Contrary to facts**, some known to McNeil at the time, it was repeatedly asserted that one of ordinary skill would not have used simethicone with an anti-diarrheal, because simethicone allegedly was not effective in treating intestinal gas. At the time of this misrepresentation, McNeil knew there were commercial simethicone anti-gas and anti-flatulent products on the market and that

simethicone had been approved as safe and effective for the treatment of flatulence and gas by the FDA. Later during prosecution, McNeil submitted numerous additional publications which were positive about the benefits of simethicone for treating intestinal gas. However, these were not submitted until after the first of the Garwin patents had issued, and after the claims of the second Garwin patent had initially been allowed.

4. **Contrary to fact**, McNeil employee Dr. Travers asserted that Clinical Study 89-950 showed that the claimed combination was surprisingly more effective than loperamide alone in treating diarrhea. Dr. Travers admitted on deposition that Clinical Study 89-950 does not support the assertion that loperamide and simethicone together are more effective in treating diarrhea than loperamide alone.

5. **Contrary to fact**, it was asserted to be surprising that the claimed combination was more effective in treating abdominal discomfort than simethicone alone. McNeil failed to inform the Patent Examiner that it was known that loperamide effectively reduced abdominal discomfort all by itself.

6. **McNeil failed to disclose** to the patent examiner the Collins reference, which was known to Dr. Garwin before his patent applications were filed. Collins taught the use of loperamide and simethicone in treating the often concurrent symptoms of diarrhea and flatulence, respectively, associated with irritable bowel syndrome.

The District Court found two of these false representations to be of critical importance, and specifically referred to a third, at pages 28a-30a of his opinion. The Federal Circuit refers to the Collins article in agreeing that the District Court's decision finding the Garwin patents invalid "was supported by clear and convincing evidence." (13a)

Material False Representation Concerning The Stevens Patent Infringement

Although not specifically cited by the District Court as being among the "further evidence warranting an award of attorneys' fees," McNeil aggressively asserted that dextrates, a principle ingredient in Perrigo's formula, are a polymeric material impermeable to simethicone oil. This assertion is directly contrary to McNeil's representations to the United Kingdom counterpart of our FDA, where it stated:

> "Dextrates. This excipient provides absorptive capacity for simethicone oil. ... As a sugar it contributes to the overall product taste."

The Federal Circuit Decision

The Federal Circuit Court of Appeals affirmed the District Court's finding that all four of the patents in suit were invalid, and that the Stevens patents were not infringed. In fact, McNeil did not appeal from the District Court finding of noninfringement of the Stevens patents.

However, the Federal Circuit reversed the District Court's award of attorney fees, stating:

> "Among the types of conduct which can form a basis for finding a case exceptional are willful infringement, inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). ... In the case of awards to prevailing accused infringers ... 'exceptional cases' are normally those of bad faith litigation or those involving fraud or inequitable conduct by the patentee in procuring the patent. *Cambridge Prods. Ltd. v. Penn Nutrients Inc.*, 962 F.2d 1048, 1050-51 (Fed. Cir. 1992). In *Revlon, Inc. v. Carson Products Co.*, 803 F.2d 676 (Fed. Cir. 1986), this court found clear error, requiring reversal, in a district court's finding a case to be 'exceptional' within the meaning of 35 USC §285 in the absence of inequitable conduct during prosecution of the patent or misconduct during litigation. *Id.* At 679. The court held that, where the existence of bad faith during proceedings before the PTO fails to rise to the level of inequitable conduct, no gross injustice is prevented by ordering payment of attorney fees and that proper application of the law dictates that the award of attorney fees be reversed. *Id.* (17a-18a)

In other words, because the District Court made no finding of "inequitable conduct" by McNeil before the PTO, the Federal Circuit Court reversed the District Court's award of attorney fees.

REASONS FOR GRANTING THE PETITION

Congress Gave District Courts Broad Discretion For Limited Use

Congress gave the district courts broad discretion in awarding attorney fees, by requiring only that the district court find the case to be "exceptional." While the word "exceptional" limits the frequency with which a court may exercise its discretion, it does not in any way particularize the circumstances upon which a court may judge a case to be "exceptional."

The Oxford English Dictionary, ©1971, defines "exceptional" in pertinent part as follows:

> Exceptional . . . out of the ordinary course, unusual, special.

Webster's Ninth Collegiate Dictionary defines the word "exceptional" in pertinent part as follows:

> 1: Forming an exception: RARE ...3: Deviating from the norm....

Thus while District Courts are permitted to award attorney fees only under circumstances which are out of the ordinary or unusual, Congress did nothing to limit or define the types of unusual facts or circumstances upon which a District Court might exercise its discretion to award attorney fees.

The Federal Circuit Has Unconstitutionally Amended 35 USC §285

The Federal Circuit has effectively amended §285 to read as follows:

> The court in *cases where there has been inequitable conduct, bad faith litigation or willful infringement,* may award reasonable attorney fees to the prevailing party.

This case is not an isolated instance of the Federal Circuit restricting the scope of discretion given trial judges by Congress under §285. McNeil accurately recited the Federal Circuit Court's legislative activity relative to §285 when it stated in its Appellate Brief at page 55:

> "This Court long ago adopted the bright line rule that in the absence of clear and convincing proof of inequitable conduct, any alleged irregularities in the PTO prosecution are irrelevant as a matter of law:
>
> > Absent proof of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules of patent examination becomes irrelevant after the patent has issued.
>
> *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997). This rule has uniformly been the law, beginning with *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 1559-60 (Fed. Cir. 1985), and confirmed in *Exxon*

Corp. v. Phillips Petroleum Co., 265 F.3d 1249, 1254 (Fed. Cir. 2001).

The Supreme Court will find that *Forest Laboratories* has on this day also filed a petition for Writ of Certiorari on precisely the same grounds upon which this Petition is based, i.e. that the Federal Circuit has improperly legislated an amendment to §285 and has improperly reversed a District Court's award of attorney fees. *Forest Laboratories Inc. v Abbott Laboratories,* 339 F.3d 1324 (Fed. Cir. 2003).

The impropriety of such judicial legislation is fundamental. Article I, Section 8 vests legislative authority with respect to patent matters in the Congress of the United States. Nothing in the Constitution of the United States gives legislative authority to the courts.

Nor can the Federal Circuit Court's decisions in these cases be construed as mere "interpretation" of the law. There is nothing to interpret. Oxford University, Merriam-Webster and other lexicographers have defined "exceptional" clearly, with synonyms such as "unusual," "out of the ordinary course," "rare," and "deviating from the norm." Limiting the factual circumstances under which a district judge may exercise its discretion to award attorney fees is not an act of interpretation of the term "exceptional." It is an act of legislation.

Abuse Of Discretion, Not Whether The Case Fits Into A Particular Box, Is The Appropriate Standard Of Review

In decisions rendered in the 1980s, the Federal Circuit demonstrates that at one time it understood the proper standard of review for reviewing judicial awards of attorney fees:

> The purpose of 35 USC §285§§ is to provide discretion to the district court where it would be grossly unjust that the winner be left to bear the burden of its own counsel fees. *Badalanenti v. Dunham's*, 896 F.2d 1359, 1364 (Fed. Cir. 1990). In order to find an abuse of discretion, this Court must find that the abuse has been unusual and exceptional -- the Court must not merely substitute its judgment for that of the Trial Judge. *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1022 (Fed. Cir. 1986). The Federal Circuit has held that the proper exercise of discretion should not be impeded by second-guessing at the appellate level. *Rosemount, Inc. v. Beckman Instr., Inc.*, 727 F.2d 1540, 1549-50 (Fed. Cir. 1984). Abuse of discretion is reflected in a definite and firm conviction that the District Court committed a clear error of judgment. *Verdegaal Bros., Inc. v. Union Oil Co.*, 750 F.2d 947, 951-52 (Fed. Cir. 1984).

Where A Litigant's Conduct Has Been Careless, Irresponsible, And Tantamount To Studied And Deceptive Ignorance, An Appellate Court Cannot Form A Definite And Firm Impression That There Has Been An Abuse Of Discretion

It is certainly unusual for a patent application to make six material misrepresentations and omissions during the course of prosecuting two closely related patent applications. Such carelessness reflects a callous disregard of United States Patent Office Rule 37 CFR 1.56, which not only proscribes inequitable conduct, but also enjoins all of those involved in the prosecution of a patent application to **exercise care.** One must exercise care in reading and representing the content of prior art references which come to their attention, and in

making representations and arguments to the Patent Office. McNeil did not exercise any such care in the present case, making five material false representations of fact, and one failure to cite a material prior art reference.

A false representation of fact is material if, ". . . it refutes, or is inconsistent with a position the Applicant takes in i) opposing an argument of unpatentability . . . or ii) asserting an argument of patentability." (37 CFR §1.56.) McNeil's argument that Garwin was the first to recognize the concurrence of diarrhea and flatulence was both an argument of patentability, and an argument opposing the Patent Examiner's assertion of unpatentability. McNeil's careless assertion that the Longe prior art reference "nowhere" discloses or recognizes "the problem of flatulence or gas associated with diarrhea," was therefore a material false representation as to the content of a prior art reference.

The materiality of McNeil's repeated assertion that Dr. Garwin was the first to combine an anti-diarrheal with simethicone is proven by the fact that the Patent Examiner gave this as his reason for allowing the second Garwin patent ('054). McNeil's failure to correct the Examiner, when it knew that the Examiner was allowing this case based on a false assumption, was a material omission compounding a material false representation.

McNeil's repeated assertion that one of ordinary skill in the art would not have used simethicone with an anti-diarrheal because simethicone allegedly was not effective in treating intestinal gas was an argument for the patentability of the Garwin patent claims. Thus McNeil's failure to point out that the FDA had approved simethicone as safe and effective for treating flatulence and gas, its failure to point out that there were numerous commercial simethicone anti-gas and anti-

flatulent products on the markets, and its later submission of numerous additional publications positive about the benefits of simethicone for treating intestinal gas, without pointing this out to the Examiner, were omissions compounding the callous carelessness of McNeil in making this false representation.

McNeil also asserted based on Clinical Study 89-950 the allegedly surprising effectiveness of loperamide and simethicone in treating diarrhea, as compared to the use of loperamide alone, as an argument for the patentability of the Garwin claims. Dr. Travers who made this assertion of surprising effectiveness in declarations to the Patent Office, admitted on deposition that Clinical Study 89-950 **does not support** the assertion of surprising and unexpected results. The representation of surprising and unexpected results as to the treatment of diarrhea was therefore also material and false.

The assertion that it was surprising that the combination of loperamide and simethicone was more effective in treating abdominal discomfort than simethicone alone was also an argument for patentability. It was therefore material, and it was false. It was known that McNeil's loperamide alone, a mild non-habitual narcotic, was effective in reducing abdominal discomfort.

Finally, Dr. Garwin failed to disclose to the Patent Office the Collins reference, which taught the use of loperamide and simethicone for treating the frequently concurrent symptoms of diarrhea and gas associated with irritable bowel syndrome. That this was a material omission is evidenced by the fact that the Federal Circuit specifically referred to the Collins reference in affirming the District Court's holding of invalidity of the Garwin patents. (13a)

Thus, McNeil made six separate material misrepresentations and omissions during the course of prosecution of the Garwin patents, as well as additional material omission related to some of the material misrepresentations. Such aggressive carelessness makes this an unusual, out of the ordinary and "exceptional case." It is not normal for patent applicants to be so aggressively careless. It is a rare, out of the ordinary circumstance.

To the extent that one believes there should be an element of "bad faith" in order for a case to be "exceptional," conduct which was "careless, irresponsible, and at the very least tantamount to studied and deceptive ignorance" qualifies as "bad faith." Careless disregard of Patent Office Rule 1.56's injunction to attorneys to be careful in prosecuting patent applications qualifies as "bad faith." While McNeil's conduct may not have been intentional, as is required for a finding of "inequitable conduct," it certainly rose to the level of "bad faith" for McNeil to have made so many false representations and omissions.

It was also bad faith for McNeil to tell the District Court that dextrates were a polymeric material impermeable to simethicone, when they knew this was not the case. They told the British counterpart of our U.S. FDA just the opposite, i.e. that dextrates are a sugar which absorb simethicone oil. While the District Court did not specifically refer to this conduct as one of the other bases justifying an award of attorney fees, it is respectfully submitted that it constitutes bad faith for McNeil to have conducted itself in this disreputable manner. Hopefully, such blatant duplicity is also unusual, out of the ordinary, and "exceptional."

The Practical Consequences Of The Federal Circuit's Legislation

Major national brand pharmaceutical companies like McNeil, a Johnson and Johnson subsidiary, have a great deal of financial incentive to 'think more aggressively about patents." Patents are a powerful tool with which to discourage or delay generic pharmaceutical companies from entering the market, giving the national brand pharmaceutical companies additional time to extract higher prices for their drugs.

This is, of course, entirely appropriate with respect to patents which are obtained by parties who have carefully apprised the Patent Office of all material facts and prior art, and have made carefully considered arguments for the patentability of their discoveries. However when acceptable aggressiveness gives way to aggressive carelessness, the results are devastating to the smaller companies. The cost of defending against charges of patent infringement is substantial, as is evidenced by the 2.1 million-dollar award of attorney fees given the Petitioners in this case. Where such patents have been improperly obtained through aggressively careless prosecution, it is entirely inappropriate and unjust that these burdensome expenses should be visited on the defendant.

The practical consequence of the Federal Circuit's legislation is that national brand pharmaceutical companies are given "cover" to aggressively carelessly prosecute patent applications, in total disregard of Patent Office Rule 1.56's requirement that applicants exercise care in prosecuting patent applications. Powerful companies are then free to use these carelessly prosecuted patents to bludgeon smaller companies

like L. Perrigo with patent litigation, without fear of consequences. This is unjust.

Certainly, no one should be punished for making an occasional unintentional mistake or misstatement of fact. However the prospect of suffering an award of attorney fees where such carelessness has been both aggressive and excessive should not be precluded by unconstitutional legislation imposed by the Federal Circuit Court. The trial judges should not be deprived of the discretion given them by Congress, in "exceptional cases," to award attorney fees under such unusual circumstances. By denying trial judges such discretion, the Federal Circuit may cause the instances of "aggressive carelessness" to increase to the point where such conduct is no longer "exceptional," but routine and normal. This would indeed be an unfortunate result.

The self restraining effect of the prospect of having to pay attorney fees for prosecuting patents which have been aggressively carelessly prosecuted should not be precluded by legislative amendment imposed on an act of Congress by the Federal Circuit Court.

CONCLUSION

Congress gave trial judges broad discretion to award attorney fees, requiring only that such discretion be exercised in "exceptional cases," that is cases which are unusual or out of the ordinary. The Federal Circuit Court has unconstitutionally amended 35 USC §285 to restrict the definition of "exceptional case" to only those cases falling into one of three specific boxes. The Federal Circuit long ago adopted the bright line rule that in the absence of clear and convincing proof of inequitable conduct, any alleged

irregularities in PTO prosecution are irrelevant as a matter of law.

It is respectfully submitted that the Federal Circuit Court is situated at the wrong end of Pennsylvania Avenue to legislate such a restriction into an Act of Congress. It is respectfully submitted that the Trial Court did not abuse its discretion in finding this case to be exceptional, based on conduct which was "careless, irresponsible, and at the very least, tantamount to studied and deceptive ignorance." It is respectfully submitted that Certiorari should be granted, and that the District Court's award of attorney fees in this case should be reinstated.

Respectfully submitted,

L. PERRIGO COMPANY AND PERRIGO COMPANY

James A. Mitchell
PRICE, HENEVELD, COOPER,
DEWITT & LITTON
695 Kenmoor, S.E.
Post Office Box 2567
Grand Rapids, Michigan 49501
(616) 949-9610

Attorneys for Petitioners,
L. Perrigo Company and Perrigo Company

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

02-1516

[Filed August 1, 2003]

MCNEIL-PPC, INC.,
Plaintiff-Appellant,

v.

L. PERRIGO COMPANY and PERRIGO COMPANY,
Defendants-Appellees.

Appealed from United States District Court
for the Eastern District of Pennsylvania
Judge Berle M. Schiller

JUDGES: Before MICHEL, Circuit Judge, ARCHER, Senior Circuit Judge, and LOURIE, Circuit Judge.

OPINION

LOURIE, Circuit Judge.

McNeil-PPC, Inc. ("McNeil") appeals from the decision of the United States District Court for the Eastern District of

Pennsylvania holding certain claims of four of McNeil's patents invalid and awarding attorney fees to L. Perrigo Company and Perrigo Company (collectively "Perrigo"). *McNeil-PPC, Inc. v. L. Perrigo* Co., 207 F. Supp. 2d 356 (E.D. Pa. 2002). Because the district court correctly determined that the asserted claims of McNeil's patents are invalid, but clearly erred in finding this to be an exceptional case within the meaning of 35 U.S.C. § 285 and awarding attorney fees to Perrigo, we affirm-in-part and reverse-in-part.

BACKGROUND

In the late 1980s, facing the then-imminent January 30, 1990 expiration of U.S. Patent 3,714,159 covering the best-selling antidiarrheal product Imodium (R) A-D, McNeil sought patentable improvements that would allow it to extend its position as market leader. *Id.* at 358- 60. Dr. Jeffrey Garwin, McNeil's assistant director of clinical research for gastrointestinal products, proposed at the time to pair loperamide, the active antidiarrheal ingredient in Imodium (R) A-D, with the antigas drug simethicone, in order to treat both diarrhea and the flatulence that often accompanies it. *Id.* at 359-60. Following Garwin's proposal, McNeil scientists evaluated a combination containing 2 mg loperamide and 125 mg simethicone, and allegedly found that the combination produced a synergistic effect. McNeil was granted two patents relating to that research: U.S. Patent 5,248,505, entitled "Method for Treating Gastrointestinal Distress," claiming methods of using compositions containing combinations of antidiarrheal compounds and simethicone to treat "a human suffering from an intestinal disorder"; and U.S. Patent 5,612,054, entitled "Pharmaceutical Compositions for Treating Gastrointestinal Distress," claiming the

antidiarrheal/simethicone compositions themselves. Collectively, the two patents are referred to as "the Garwin patents." *Id.* at 360.

Further research with chewable tablets containing a combination of loperamide and simethicone led to the discovery that the simethicone in those tablets apparently "surrounded" the loperamide over time, decreasing its bioavailability, and thereby reducing the tablets' shelf-life. *Id.* at 359, 366. McNeil researchers Charles Stevens, Michael Hoy, and Edward Roche then found that the decrease in bioavailability could be avoided by using a polymeric barrier to separate the simethicone from the loperamide. *Id.* at 367-68. Subsequently, McNeil obtained U.S. Patents 5,716,641 and 5,679,376 (both entitled "Simethicone Containing Pharmaceutical Compositions," and collectively referred to as "the Stevens patents"), covering that method and the resulting tablets, respectively. *Id.* at 366-67. McNeil has sold loperamide/simethicone combination tablets having the impermeable barrier of the '376 and '641 patents as Imodium (R) Advanced since 1997, pursuant to an approved New Drug Application ("NDA").

Perrigo filed an Abbreviated New Drug Application ("ANDA") at the United States Food and Drug Administration ("FDA") in 2000 under 21 U.S.C. § 355(j), seeking approval to market a generic version of *Imodium (R) Advanced*. *Id.* at 359. Along with the bioavailability/bioequivalency test data that it was required to include in its ANDA, Perrigo filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (i.e., a "paragraph IV certification"), declaring that the Garwin patents are invalid; that the Stevens patents are invalid; and that Perrigo's

proposed manufacture, use, and sale of its loperamide/simethicone combination product would not infringe the Stevens patents. As required under 21 U.S.C. § 355(j)(2)(B), Perrigo also gave notice of its ANDA filing to McNeil as the patent owner and NDA holder, providing a detailed statement of the factual and legal bases for Perrigo's opinion that the Garwin and Stevens patents are invalid and that the Stevens patents would not be infringed if its product were to be approved for marketing. *Id.*

On March 7, 2001, McNeil filed suit against Perrigo under 35 U.S.C. § 271(e)(2)(A), alleging that Perrigo's submission of its ANDA was an act of infringement of numerous claims of the Garwin and Stevens patents. Id. McNeil later amended its complaint twice, ultimately asserting infringement of only claims 14 and 16 of the '505 patent, claim 15 of the '054 patent, claims 1 and 2 of the '376 patent, and claims 1-3 of the '641 patent under § 271(e)(2)(A). *Id.* The asserted claims of the '505 patent read as follows:

> 14. [A method for treating a human suffering from an intestinal disorder characterized by the symptoms of diarrhea and flatulence or gas comprising administering to said human in a combined pharmaceutical composition, an effective amount of an antidiarrheal compound selected from the group consisting of loperamide, bismuth subsalicylate, diphenoxylate, polycarbophil, their pharmaceutically acceptable salts and mixtures thereof; and an antiflatulent effective amount of simethicone,] wherein the amount of simethicone administered is 125 mg per

> dosage unit and the amount of loperamide administered is 2 mg per dosage unit.[1]
>
> 16. A method for treating a human suffering from an intestinal disorder characterized by diarrhea and flatulence and or gas comprising administering to said human in a combined pharmaceutical composition, 4 mg of loperamide and an antiflatulent effective amount of simethicone; thereafter administering to said human in a combined pharmaceutical composition, 2 mg of loperamide and an antiflatulent effective amount of simethicone until the diarrhea is controlled.

The asserted claim of the '054 patent reads as follows:

> 15. [A composition for treating a human suffering from an intestinal disorder characterized by the symptoms of diarrhea and flatulence or gas comprising: an effective amount of an antidiarrheal compound selected from the group consisting of loperamide, bismuth subsalicylate, diphenoxylate, polycarbophil, their pharmaceutically acceptable salts and mixtures thereof; and an antiflatulent effective amount of simethicone,] comprising 125 mg of simethicone and 2 mg of loperamide.[2]

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[1] Claim 14 of the '505 patent depends from claim 2, which in turn depends from claim 1, and the relevant portions of those independent claims are shown in brackets above.

[2] Claim 15 of the '054 patent depends from claim 2, which in turn depends from claim 1; the relevant portions of those independent claims are shown in brackets above.

The asserted claims of the '641 patent read as follows:

> 1. A method of enhancing the dissolution profile of a pharmaceutical from a solid dosage form comprising the pharmaceutical and simethicone, comprising: providing the pharmaceutical in a first portion of said dosage form, said pharmaceutical is selected from the group consisting of diphenoxylate, loperamide and loperamide-N-oxide, pharmaceutically acceptable salts thereof, and combinations thereof; providing the simethicone in a second portion of said dosage form; and separating said first and second portions with a pharmaceutically acceptable polymeric barrier which is impermeable to simethicone and the pharmaceutical.
>
> 2. The method of claim 1 wherein the pharmaceutical is selected from the group consisting of loperamide, loperamide-N-oxide, pharmaceutically acceptable salts thereof and combinations thereof.
>
> 3. The method of claim 1 wherein the pharmaceutical comprises loperamide Hcl.

The asserted claims of the '376 patent read as follows:

> 1. A solid oral dosage form for the treatment of gastrointestinal distress comprising a therapeutically effective amount of a pharmaceutical for the treatment of gastric disorders selected from the group consisting of diphenoxylate, loperamide, loperamide-N-oxide, pharmaceutically acceptable salts thereof, and combinations thereof; and a therapeutically effective amount of simethicone wherein the oral dosage form

> has a first portion containing the pharmaceutical and a second portion containing simethicone and the first and second portions are separated by a pharmaceutically acceptable polymeric barrier, which is impermeable to simethicone and the pharmaceutical.
>
> 2. The solid oral dosage form of claim 1 wherein the pharmaceutical comprises loperamide Hcl.

Following a bench trial, the district court concluded that the asserted claims of the Garwin patents were obvious over three prior art references: an Australian pharmaceutical reference publication entitled "Mims Annual 1980, Section 1e Antidiarrheals," which discloses a product called Diareze that combines the antidiarrheal compound attapulgite with simethicone "to help relieve the pain and discomfort of gaseous distention"; French Patent Application 2,565,107, which discloses the use of simethicone and activated charcoal, also a known antidiarrheal; and U.S. Patent 4,980,175 (the "Chavkin patent"), which discloses combinations of various substances, including the antidiarrheal polycarbophil and simethicone. *Id.* at 362. The court found that one of skill in the art at the time of the inventions would have known that flatulence commonly accompanies diarrhea, and concluded that it would have been obvious to replace attapulgite, activated charcoal, or polycarbophil in the prior art references with loperamide, which was, after all, the active ingredient in the best-selling antidiarrheal drug, to treat both diarrhea and gas. *Id.* at 364. The court discounted the value of McNeil's objective evidence, including evidence of unexpected results, commercial success, and copying by others, and held the asserted claims invalid. *Id.* at 371-72.

The district court then concluded that the product for which Perrigo was seeking FDA approval would not infringe the Stevens patents, because that product directly juxtaposes loperamide and simethicone layers without any impermeable polymeric barrier between them. *Id.* at 367-68, 372-73. The court held that the asserted claims of the Stevens patents were, in any event, also invalid for obviousness over the Garwin patent applications, which taught making tablets having separate loperamide and simethicone layers, in view of the prior art U.S. Patent 4,198,390 (the "Rider patent"), which taught the use of an impermeable polymeric barrier to prevent migration and deactivation of simethicone in simethicone-containing antacid tablets. *Id.* at 368-69, 373.

Finally, the district court awarded attorney fees to Perrigo, stating that McNeil's conduct during prosecution of the patents in suit was "careless, irresponsible, and, at the very least, tantamount to studied and deceptive ignorance." *Id.* at 374. According to the court, "McNeil's repeated erroneous representations, failure to disclose relevant prior art, and overall persistence in prosecuting exceedingly obvious 'inventions' make this case exceptional." *Id.* The court accused McNeil of having engaged in "a scheme for extending the life of a drug about to go off patent . . . without the slightest regard for the intent and purposes of the patent laws," and found that "McNeil's sole motive was to compromise [those] statutes and constitutional protections for the sake of profits." *Id.*

The district court concluded its opinion with a discussion of the constitutional basis for the patent system and what it perceived to be a deviation from the original purposes of that system by business-driven decisions. According to the court:

The patent laws "promote the Progress of Science and useful Arts" by rewarding innovation with a temporary right to exclusivity. U.S. Const., art. I, § 8, cl. 8. . . . Long ago, in *Hotchkiss v. Greenwood*, 52 U.S. 248, 11 How. 248, 267, 13 L. Ed. 683 (1851), the Supreme Court established that the sine qua non of patentability is invention, and as stated in 35 U.S.C. § 100(a), the legal definition of invention is synonymous with discovery. . . . Over time, patent law has developed its own, new language, and has even come to require special qualifications for lawyers appearing before the PTO. These developments tend to obscure the fundamental notions of invention and discovery.

Acting within this often esoteric area of the law, patent lawyers are called upon to play the roles of chemists, engineers, physicians, and physicists - now, they are also asked to be magicians. That is, patent lawyers are asked to defend - with smoke and incantations when necessary - business-driven decisions having nothing to do with inventing or discovering anything. Consistent with schemes to prolong the legally[ ] protected period of exclusivity, companies hire highly talented attorneys to perform acts of legal legerdemain in order to make modest developments look and feel like inventions, when in reality the purported discovery is nothing more than a creation of an advertising and marketing department. In- house counsel should be cautioned that complicity in patent prosecution for unsanctioned legal purposes may give rise in the future to review of that behavior by the appropriate attorney disciplinary machinery.

> Advancing a client's economic interests is not a license to forget one's ethical responsibilities.
>
> It is not lost on this Court that by developing ("not inventing") a combination drug, the law automatically permitted McNeil a three-year period of exclusivity . . . . However, by concocting multiple patent applications and litigating their validity, this period of exclusivity has been extended by two years and, with an appeal, will extend even further, effectively doubling the initial period of exclusivity. The business-driven decision that it is worth the investment to "invent an invention" will continue unabated unless a vigorous PTO or a Court sees this transparent attempt to subvert the patent laws for what it is. The patent laws are not the private sandbox of pharmaceutical companies. Regrettably, I am constrained by law to award only counsel fees for Plaintiff's behavior, although I am not unmindful of the fact that while this patent litigation continues, competition in the marketplace is foreclosed and the public is forced to pay higher prices.

Id. at 374-75.

McNeil now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

McNeil appeals the district court's holding that the asserted claims of the Garwin and Stevens patents are invalid

for obviousness. McNeil also appeals the court's award of attorney fees to Perrigo.

A. Obviousness

Obviousness is a legal conclusion based on the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *Id.* at 17-18. When reviewing a district court's decision, we review a district court's underlying findings of fact for clear error, while we rule de novo on the ultimate issue of obviousness. *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1355 (Fed. Cir. 1999).

On appeal, McNeil argues that the district court erred by holding the asserted claims of the Garwin patents invalid for obviousness. In particular, McNeil contends that the prior art failed to provide any disclosure of or motivation to make the claimed combination. According to McNeil, the court committed several legal errors in its obviousness analysis. First, McNeil alleges, the court defined the problem to be solved in terms of its solution. According to McNeil, the problem was not how to "make a combination that treats diarrhea and gas," but how to treat diarrhea and gas. Second, McNeil argues, the court employed an improper "obviousness of substitution approach," and judged the invention on the subjective motives of the inventor and his employer, rather than on its merits. Third, with respect to the references cited by the district court, McNeil argues that the Mims reference and the French patent were both before the PTO during

prosecution of the Garwin patent application[3] and that the Chavkin patent, the only prior art cited by the court that was not before the PTO, merely describes "liquid carriers for administration of . . . compositions." Although the Chavkin patent mentions both polycarbophil (termed a "bio-adhesive agent" in the reference) and simethicone, McNeil contends that it does not suggest using both in a single composition. According to McNeil, the court's conclusion that it would have been obvious to combine loperamide with simethicone because diarrhea is often accompanied by flatulence totally disregards evidence that (1) simethicone was not generally believed to be an antiflatulent; and (2) flatulence and diarrhea were never separately treated before the invention because loperamide itself relieves flatulence by treating the underlying diarrhea. McNeil argues that the court's finding that simethicone was a known antiflatulent is clearly erroneous, because simethicone was known to be an "antigas" agent only because it stimulates burping and belching, and thereby helps relieve stomach, i.e., gastric, gas. However, flatulence is caused by intestinal gas, McNeil contends, and stimulating the passing of that gas would exacerbate flatulence. Lastly, McNeil asserts that the court also failed to give proper weight to undisputed objective evidence of nonobviousness, including unexpected results and copying, discounting that evidence without any good reason.

Perrigo responds that the district court's decision is supported by clear and convincing evidence of obviousness.

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[3] Perrigo points out that McNeil actually cited to the PTO a 1989 Mims reference, not the 1980 Mims reference referred to by the district court. It appears, however, that the relevant portions of the disclosures of those two references are the same.

Moreover, according to Perrigo, McNeil does not challenge as clearly erroneous any of the court's factual findings other than those relating to secondary considerations, but instead attempts to propose on appeal numerous new findings of fact that either are not supported by the record or else are plainly contrary to the court's findings. Perrigo also points out that Stephen M. Collins, The Irritable Bowel Syndrome, 138 Can. Med. Ass'n J. 309 (1988), an article referenced in Garwin's laboratory notebook but not cited to the PTO, teaches treatment of irritable bowel syndrome with both loperamide and simethicone.

We agree with Perrigo that the district court's decision was supported by clear and convincing evidence. The court found, in particular, that the concurrence of diarrhea and flatulence had been noted in more than twenty prior art articles and publications, *McNeil*, 207 F. Supp. at 361; that a 2-4 mg dose of loperamide was known to be a commercially successful and effective antidiarrheal, and simethicone was a well-known antiflatulent sold in more than twenty-five different products (some including a 125 mg dose), by the time of Garwin's alleged invention, *id.* at 362; and that combinations of several other well-known antidiarrheals with simethicone had been described in the prior art, even if they had not been commercialized, *id.* Thus, the district court found that all of the limitations in the asserted claims of the Garwin patents were known and that there was motivation to combine those elements as of Garwin's asserted invention date. We see no error in the court's determination.

We also agree with Perrigo that the district court properly discounted the probative value of McNeil's asserted evidence of secondary indicia of nonobviousness. The court found that

McNeil had launched a massive marketing and advertising campaign in connection with the launch of the Imodium (R) Advanced product, obscuring any nexus that might have existed between the merits of the product and its commercial success. *Id.* at 364-65. The court also found that the article cited by McNeil as demonstrating that simethicone did not reduce intestinal gas was based on the results of a study involving only nine participants and thus did not rise to the level of statistical significance. *Id.* at 362 n.13. Finally, the court found that the results of clinical studies adduced by McNeil were inconsistent, not shown to be reproducible, and did not include comparative data vis-a-vis placebos or other antidiarrheal/antiflatulent combinations necessary to demonstrate unexpected or synergistic effects. On the basis of the district court's findings, which reflect clear and convincing evidence of obviousness, we affirm the court's decision holding claims 14 and 16 of the '505 patent and claim 15 of the '054 patent invalid.

McNeil next argues that the district court erred by holding the asserted claims of the Stevens patents invalid for obviousness. According to McNeil, the Rider patent described using an impermeable polymeric barrier to prevent inactivation of simethicone by antacids, not to prevent coating of loperamide by simethicone. In concluding that Stevens's invention would have been obvious, McNeil contends, the court failed to consider that neither the Garwin patents nor the Rider patent identified the problem solved by Stevens, i.e., the short shelf life of loperamide in combination tablets with simethicone. McNeil cites *In re Zurko*, 111 F.3d 887 (Fed. Cir. 1997), and *In re Sponnoble*, 56 C.C.P.A. 823, 405 F.2d 578 (CCPA 1969), for the proposition that an invention may be patentable even if "the remedy may be obvious once the

source of the problem is identified." According to McNeil, the prior art failed to identify the problem, and the claims of the Stevens patents must therefore have been nonobvious. Perrigo responds by arguing that the court's unchallenged factual findings supports the conclusion of obviousness.

We agree with Perrigo that the evidence clearly and convincingly supports the district court's conclusion. The district court found that the Garwin patents taught both the combination of loperamide and simethicone, and the separation of those two ingredients into different layers of a tablet. The court also found that the Rider patent taught that simethicone could be kept separated from other active ingredients in combination products using an impermeable polymeric barrier. McNeil does not challenge those factual findings. Although, as McNeil points out, the Rider patent did not disclose the specific interaction of simethicone with loperamide, we see no error in the district court's finding that the Rider patent provided motivation to include an impermeable polymeric barrier to prevent simethicone migration from one layer to an adjacent pharmaceutical-containing layer. McNeil's arguments to the contrary are unconvincing. On the basis of those findings, and in view of the lack of any significant objective evidence of nonobviousness, we affirm the court's conclusion that claims 1-3 of the '641 patent and claims 1 and 2 of the '376 patent are invalid for obviousness.

B. Attorney Fees

McNeil argues that the district court abused its discretion by awarding attorney fees to Perrigo. Paraphrasing this court's precedent, McNeil argues that an award of attorney

fees under § 285 to an accused infringer may be based on only two grounds: (1) inequitable conduct in the PTO, and (2) bad faith litigation. Neither of those applies in this case, according to McNeil, and there is no other legally cognizable basis to grant attorney fees to an accused, but prevailing, infringer. McNeil also alleges that the district court erroneously buttressed its award of attorney fees by finding that McNeil had benefited by invoking the Hatch-Waxman Act's stay provisions codified at 21 U.S.C. § 355(j)(5)(B)(i). According to McNeil, it is undisputed that McNeil did not and has not invoked the stay provisions of that Act. Notwithstanding the fundamental premise of the patent laws that the profit motive provides a critical incentive to invent, McNeil argues, the court characterized McNeil's legitimate business decisions as an attempt to "subvert the patent laws" and criticized McNeil's inventions as part of "a scheme." McNeil also alleges that the court's "unwarranted attack" on McNeil has encouraged a host of misplaced antitrust actions filed against McNeil.

Perrigo responds by arguing that McNeil's attorneys made false representations during the seven years of prosecution of the Garwin patents, including assertions that Garwin had discovered the concurrence of diarrhea and flatulence, that Garwin was the first to combine an antidiarrheal with simethicone, that simethicone was believed to be ineffective at treating flatulence, and that the combination of loperamide and simethicone displayed synergistic effects; and failed to disclose the Chavkin patent, the Collins article, and the 1980 Mims reference. The court's finding that McNeil aggressively prosecuted the Garwin patent applications in "studied and deceptive ignorance" is well supported, according to Perrigo, and is not clearly erroneous. McNeil's claim of infringement

of the Stevens patents, made without McNeil's having conducted even the most rudimentary examination of Perrigo's product, by itself justifies the award of attorney fees, Perrigo contends. Finally, Perrigo's attorney, during oral argument in this appeal, suggested that attorney fees are warranted in this case on the ground of "aggressive carelessness" on the part of McNeil during patent prosecution, and that we should accordingly affirm the district court's award of fees to Perrigo.

The court in exceptional cases may award reasonable attorney fees to a prevailing party. 35 U.S.C. § 285 (2000). "Among the types of conduct which can form a basis for finding a case exceptional are willful infringement, inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Evidence of such conduct must be supported by clear and convincing evidence. *Id.* "In the case of awards to prevailing accused infringers . . . 'exceptional cases' are normally those of bad faith litigation or those involving fraud or inequitable conduct by the patentee in procuring the patent." *Cambridge Prods. Ltd. v. Penn Nutrients Inc.*, 962 F.2d 1048, 1050-51 (Fed. Cir. 1992). In *Revlon, Inc. v. Carson Products Co.*, 803 F.2d 676 (Fed. Cir. 1986), this court found clear error, requiring reversal, in a district court's finding a case to be "exceptional" within the meaning of 35 U.S.C. § 285 in the absence of inequitable conduct during prosecution of the patent or misconduct during litigation. *Id.* at 679. The court held that, where the existence of bad faith during proceedings before the PTO fails to rise to the level of inequitable conduct, no gross injustice is prevented by ordering payment

of attorney fees, and that proper application of the law dictates that the award of attorney fees be reversed. *Id.* Although "the trial judge may exercise his discretion to award attorney fees and costs because of inequitable conduct during prosecution of the patent or misconduct during litigation . . . [, a]ttorney fees are not to be routinely assessed against a losing party in litigation in order to avoid penalizing a party 'for merely defending or prosecuting a lawsuit.'" *Id.* (quoting *Fleischmann Distilling Corp. v. Maier Brewing Co.*, 386 U.S. 714, 718, 18 L. Ed. 2d 475, 87 S. Ct. 1404 (1967)).

We have not previously held any party liable for attorney fees for either vigorously prosecuting its patent application or enforcing a presumptively valid patent, even where that patent was later invalidated, in the absence of clear and convincing evidence of inequitable conduct or misconduct during litigation. We decline Perrigo's invitation to do so on these facts. The district court did not find that McNeil's conduct during litigation was egregious or that its patent prosecution rose to the level of inequitable conduct, and we find no other basis for finding this to be an "exceptional" case. A patent owner has the "right to exclude others from making, using, and selling the invention and to enforce those rights until [its patents are] held invalid [or expire]." *Concrete Unlimited Inc. v. Cementcraft, Inc.*, 776 F.2d 1537, 1539 (Fed. Cir. 1985). That right is not unlimited; bad faith litigation, where a patentee initiates litigation on a patent he knows is invalid or is not infringed, is conduct offensive to public policy, *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 875-76 (Fed. Cir. 1985), and can provide a basis for granting attorney fees.

Given the existence of patents issued by the PTO with a presumption of validity, the present lawsuit was not found to

have been brought in bad faith. It is noteworthy in that regard that Perrigo did not challenge McNeil's claims of infringement of the Garwin patents, and that, although Perrigo calls McNeil's claim of infringement of the Stevens patents "outrageous," the record reflects that McNeil's experts advanced a plausible theory of infringement of those claims as well. The district court specifically found that "Perrigo's product does contain polymeric materials," *McNeil*, 207 F. Supp. 2d at 367 n.25, but ultimately concluded that that product would not infringe because it does not contain an impermeable barrier as required by the asserted claims. The district court found that the parties "essentially agreed" that the question whether Perrigo's ANDA product would infringe the Stevens patents "turns solely on whether the Perrigo's [sic] ANDA product employs an impermeable polymeric barrier," which in turn appears to have turned merely on the court's construction of that term. *Id.* at 368. Moreover, although the claims at issue have now been held to be invalid, they had not been held to be invalid at the time that they were asserted against Perrigo. The present fact of their invalidity cannot be used to bootstrap the argument that they were asserted in bad faith, absent clear and convincing evidence that McNeil had reason to believe that the claims were invalid or not infringed.

The district court was notably disturbed that McNeil set out as an objective developing products that extended the life of their basic patent on loperamide. Its concern was with McNeil's objective to obtain additional patent protection on an invention whose patent was about to expire, more than with its conduct in doing so. Short of inequitable conduct or litigation misconduct, neither of which was found here, however, McNeil was entitled to file patent applications on

what it considered to be patentable inventions (in fact, the PTO did grant those patents). While it may be considered more socially desirable for companies to seek truly novel inventions for maladies not yet treatable, the patent laws set the standards of novelty, non-obviousness, and utility as the requirements for patentability, without making value judgments concerning the motives for making and attempting to patent new inventions of lesser medical value. Thus, as no inequitable conduct, or litigation or other misconduct, was found, the exceptional case finding of the district court cannot stand. Accordingly, we reverse the district court's grant of attorney fees to Perrigo.

CONCLUSION

The district court did not err in holding the asserted claims of McNeil's '505, '054, '376, and '641 patents invalid, but clearly erred in finding this to be an exceptional case under 35 U.S.C. § 285 and awarding attorney fees to Perrigo. The court's decision is therefore

AFFIRMED-IN-PART and REVERSED-IN-PART.

COSTS

Each party to bear its own costs.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CIVIL ACTION No. 01-1100

[Filed June 25, 2002]

MCNEIL-PPC, INC.,)
Plaintiff,)
)
v.)
)
L. PERRIGO COMPANY,)
and PERRIGO COMPANY,)
Defendants.)
)

JUDGES: Berle M. Schiller, J.

OPINION AND ORDER

SCHILLER, J.

This is a patent infringement action. Plaintiff McNeil-PPC, Inc. ("McNeil") alleges Defendants L. Perrigo Company and Perrigo Company (collectively "Perrigo") infringe four McNeil patents covering a popular version of the Imodium (R) Advanced antidiarrheal. In a Memorandum and Order issued April 3, 2002, I construed certain disputed claim terms pursuant to *Markman v. Westview Instruments, Inc.*,

517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). Beginning April 22, 2002, this matter was tried without a jury, and I enter the following Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure.[1]

FINDINGS OF FACT

1. BACKGROUND

This action pits a manufacturer of national brand pharmaceuticals against its competitor, a generic drug manufacturer. Four patents owned by Plaintiff McNeil are at issue in this case: United States Patents 5,248,505 ("the '505 patent")(PTX1) and 5,612,054 ("the '054 patent")(PTX2) are referred to as "the Garwin patents";[2] United States Patents 5,679,376 ("the '376 patent")(PTX3) and 5,716,641 ("the '641 patent")(PTX4) are referred to as "the Stevens patents."

1. Plaintiff's Product and the Patents in Suit

Plaintiff McNeil is a subsidiary of a well-known multi-billion-dollar company, Johnson & Johnson. Among other things, McNeil sells over-the-counter ("OTC")

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[1] This action arises under the patent laws of the United States. *See* 35 U.S.C. § 271(e)(2) and 21 U.S.C. § 355(j). Jurisdiction is based on 28 U.S.C. § § 1331 and 1338(a). Venue is proper in this Court pursuant to 28 U.S.C. § § 1391(c) and 1400(b).

[2] The '505 patent covers a method for treating gastrointestinal distress; the '054 patent covers the related pharmaceutical composition.

pharmaceuticals, including Tylenol (R) and Motrin (R) . (Eble TT at 58.)[3] McNeil's products can be found in nearly every pharmacy in the United States. (Eble TT at 77-79.)

An antidiarrheal drug known as loperamide is central to this matter. Loperamide, a non-addictive opiate, is believed to treat diarrhea in a number of ways, including: regulating muscular contractions in the intestine, limiting secretions in the intestinal tract, and relieving abdominal discomfort. (Levitt TT at 621-22; PTX721; DX157 at 37.)[4] Also important to the instant controversy is an oily liquid substance known as simethicone, which is employed as an antiflatulent. (Garwin TT at 137.)

During the 1980s, loperamide became the best-selling prescription antidiarrheal in the United States. (Snape TT at 1219.) In March 1988, McNeil began selling loperamide as the OTC product Imodium A-D. With the January 30, 1990 expiration date for the basic loperamide patent fast approaching, McNeil directed one of its scientists, Dr. Jeffrey Garwin, to develop a new patent-protected form of loperamide. (Garwin TT at 133.) Pursuing this directive, Dr. Garwin developed a drug that combined loperamide with simethicone, and his resulting patent application, along with continuation applications, led to the issuance of the two

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[3] The trial transcript is cited in the following format: (name of witness) TT at (transcript page(s)).

[4] Many exhibits contain multiple page number designations. Where more than one designation is present, the clearest page number designation is cited.

Garwin patents: the '505 patent on September 28, 1993 and the '054 patent on March 18, 1997. (PTX1, 2.)

McNeil initially marketed the loperamide-simethicone combination drug as the Imodium Advanced chewable tablet. In developing the Imodium Advanced tablet, McNeil researchers became concerned that over time the simethicone interacted negatively with the loperamide, limiting the drug's shelf life. (Schwartz TT at 433.) In response, Dr. Charles Stevens and other McNeil researchers considered different ways of keeping an antidiarrheal separated from simethicone. (Schwartz TT at 438-39.) This work became the basis for the Stevens patents. (PTX3, 4.)

2. Perrigo's Abbreviated New Drug Application ("ANDA") and the Instant Litigation

With sales exceeding $ 800 million per year, Defendant Perrigo is the world's largest manufacturer of store brand - commonly referred to as "generic" - OTC pharmaceutical products. (Needham TT at 798, 800, 804; DX158.) Major retail chains such as Wal-Mart, Rite-Aid, and CVS sell Perrigo's products under their stores' respective labels. (Needham TT at 800, 803.) Perrigo's store brand products generally cost thirty to forty percent less than corresponding national brand products. (Needham TT at 800.)

Perrigo competes with McNeil in the antidiarrheal market. After the basic loperamide patent expired in the late 1980s, Perrigo began marketing a store brand loperamide product similar to McNeil's Imodium-A-D tablet. (Needham TT at 813-14.) When McNeil introduced the Imodium Advanced combination drug, Perrigo became interested in developing a

loperamide-simethicone product in order to better compete in the antidiarrheal market. (Needham TT at 814-15.) Pursuing this interest, Perrigo consulted outside patent counsel, who rendered a final opinion that Perrigo's proposed loperamide-simethicone product would not infringe the Stevens patents and that the Garwin patents were invalid. (Needham TT at 823-27.)

In November 2000, Perrigo filed an Abbreviated New Drug Application with the FDA seeking the approval of a loperamide-simethicone combination tablet. Thereafter, Perrigo sent a Patent Certification Notice Letter informing McNeil that McNeil's patents were invalid or not infringed by Perrigo's ANDA drug. (PTX14.) On March 7, 2001, McNeil filed suit against Perrigo, alleging the infringement of a host of patent claims. Subsequently, McNeil twice amended its complaint, narrowing the patent claims at issue.

2. The Garwin Patents

Upon its approval by the Food and Drug Administration ("FDA") in 1977, Janssen Pharmaceutica ("Janssen"), a Johnson & Johnson subsidiary, began selling loperamide as a prescription drug. (Eble TT at 65; DX16 at MC13403-06.) McNeil inherited loperamide from Janssen. After loperamide was approved as an OTC drug in 1988, McNeil began selling loperamide as Imodium A-D. (Eble TT at 65-66; DX16 at MC13404.) With the basic loperamide patent[5] set to expire within two years of McNeil's launch of Imodium A-D, McNeil asked Dr. Garwin "to come up with a patent-

[5] United States Patent 3,714,159 (DX104.)

protected form of Imodium." (Garwin TT at. 131; DX104) Additionally, following McNeil's involvement in litigation that resulted in the invalidation of a patent combining ibuprofen and pseudoephedrine, *see Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476 (Fed. Cir. 1997), Dr. Garwin was instructed "to think more aggressively about patents." (Garwin TT at 123-24; DX6 at MC73095). Dr. Garwin described McNeil's reaction to the *Richardson-Vicks* litigation as follows:

> There was concern at McNeil that there might be other sleeper patents out there that could inhibit McNeil's ability to work in the area where McNeil was already working or planning to work, and if there were patents to be had, McNeil wanted to have - wanted us to think of them first.

(Garwin TT at 123.)

Following these instructions, Dr. Garwin considered whether a loperamide-based product could relieve certain diarrhea-related symptoms such as flatulence. (Garwin TT at 115-16.) On November 1, 1989, Dr. Garwin filed his first patent application, claiming the combination of simethicone with certain antidiarrheals, including loperamide. (PTX5 at 20-22.)[6]

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[6] In each of the four patents in suit, loperamide is among a list of antidiarrheals that may be combined with simethicone. No evidence suggests, however, that McNeil seriously considered any antidiarrheal other than loperamide for its Imodium products.

A. The Garwin Patents' Claims at Issue

Claims 14 and 16 of the '505 patent and claim 15 of the '054 patent are at issue. These claims read as follows:

The '505 Patent[7]

> A method for treating a human suffering from an intestinal disorder characterized by the symptoms of diarrhea and flatulence or gas comprising administering to said human in a combined pharmaceutical composition, an effective amount of an antidiarrheal compound selected from the group consisting of loperamide, bismuth subsalicyclate, diphenoxylate, polycarbophil, their pharmaceutically acceptable salts and mixtures thereof; and an antiflatulent effective amount of simethicone, wherein the amount of simethicone administered is 125 mg per dosage unit and the amount of loperamide administered is 2 mg per dosage unit.

Claim 15 of the '054 Patent[8]

> A composition of treating a human suffering from an intestinal disorder characterized by the symptoms of diarrhea and flatulence or gas comprising: an effective amount of an antidiarrheal compound

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[7] Claim 14 of the '505 patent incorporates claims 1 and 2 and is set forth accordingly herein to include these limitations.

[8] Claim 15 of the '054 patent incorporates claims 1 and 2 and is set forth accordingly herein to include these limitations.

selected from the group consisting of loperamide, bismuth subsalicyclate, diphenoxylate, polycarbophil, their pharmaceutically acceptable salts and mixtures thereof; and an antiflatulent effective amount of simethicone, comprising 125 mg of simethicone and 2 mg of loperamide.

2. Prosecution History[9]

During the course of the lengthy prosecution of the Garwin patents, McNeil's attorneys[10] made a number of erroneous representations. Two such representations are of critical importance. First, McNeil incorrectly argued to the

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[9] McNeil argues that in the absence of inequitable conduct, evidence relating to improper patent prosecution is irrelevant. This argument appears to miss the mark. *See Applied Materials v. Advanced Semiconductor Materials Am.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996)("facts relevant to the issue of obviousness were before the district court, including . . . prosecution history in the PTO"). In any event, what happened before the PTO in this case does not affect the statutory presumption that the Garwin patents are valid. The discussion of the prosecution history is primarily intended to highlight fundamental flaws in McNeil's contention that the Garwin patents are nonobvious. Lastly, the history of the Garwin patents' prosecution reveals that certain comments made by Judge Learned Hand seventy-five years ago are no less apt today: "The antlike persistency of [patent] solicitors has overcome and . . . will continue to overcome, the patience of examiners, and there is apparently always but one outcome." *Lyon v. Boh*, 1 F.2d 48, 50 (S.D.N.Y. 1924).

[10] McNeil's trial counsel did not represent McNeil during the prosecution of the Garwin or Stevens patents.

Patent and Trademark Office ("PTO") that Dr. Garwin had discovered the concurrence of diarrhea and flatulence:

> It is Applicant's recognition of this problem, i.e., the concurrence of diarrhea and flatulence as indicated in a proprietary survey of patents which forms the basis of the present invention. The invention, therefore, lies not in the discovery of a novel solution to this problem, but in the discovery of the problem itself.

(DX12, p. 48, 67.)

Although his belief to contrary may have been sincere, Dr. Garwin did not discover the concurrence of diarrhea and gas. Moreover, with the exception of a relatively obscure reference in the *Handbook of Nonprescription Drugs* ("Longe reference")(DX12 at 326), McNeil's attorneys failed to provide the Examiner with evidence that would have called into question McNeil's assertion that Dr. Garwin had discovered the concurrence of diarrhea and flatulence.[11] In fact, as identified by one of Perrigo's experts, Dr. Michael Levitt, more than twenty prior art articles and publications

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[11] The Longe reference states: "Acute diarrhea is characterized by a sudden onset of frequent, liquid stools accompanied by weakness, flatulence, pain, and often fever and vomiting." (DX12 at 326). In this regard, it is noteworthy that McNeil's attorneys did not point out this statement to the Examiner. Instead, they cited the Longe reference because it "discloses antidiarrheal and other gastrointestinal products. No suggestion is made for combining antidiarrheal with antiflatulent compositions." (*Id.* at 26.)

noted the concurrence of diarrhea and gas-related symptoms. (Levitt TT at 711; PTX420 at 15-18.) As an important example, in the 1983 edition of Sleisenger and Fordtran's leading textbook, *Gastrointestinal Disease*, a chapter entitled "Infectious Diarrhea," authored by Dr. Sherwood Gorbach ("Gorbach reference"), included a table indicating that gas was associated with traveler's diarrhea in seventy-nine percent of occurrences. (Snape TT at 1172, 1205; DX84-1 at 953.)[12]

Second, McNeil's attorneys permitted the Examiner to believe mistakenly that Dr. Garwin was the first to combine an antidiarrheal with simethicone. In allowing the '054 patent application to issue, the Examiner stated: "The present application . . . is allowable because there was not any prior art or references showing a composition comprising an effective amount of an antidiarrheal compound and an antiflatulent compound." (DX13 at 186.) Despite having an opportunity to comment on the Examiner's reasons for allowance, McNeil failed to take any action to correct this error. (DX13 at 184.) More importantly, as is explained below, prior art - including prior art not presented to the Examiner - disclosed such a combination.[13]

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[12] Traveler's diarrhea is one of the most common forms of diarrhea, affecting millions of people annually. (DX84-1 at 953.)

[13] McNeil made other erroneous representations during the prosecution of the Garwin patents. For example, while prosecuting the Garwin patents McNeil misleadingly relied on an article that found that simethicone did not reduce gas in the colon ("Jain article"). (DX12 at 180-81.) The results reported in the Jain article, however, were based on a study involving only nine participants and did not rise to the level statistical significance. Other studies,

3. Scope and Content of the Prior Art

1. Antidiarrheals and Antiflatulents at the Time of Dr. Garwin's Alleged Discovery

By the time of the claimed invention, one of ordinary skill in the art would have known that loperamide was a commercially successful antidiarrheal. (Levitt TT at 585, 596-97.) Additionally, by the time of Dr. Garwin's alleged discovery, compounds such as attapulgite, polycarbophil, bismuth subsalicyclate, and activated charcoal were well-known antidiarrheals among those of ordinary skill in the art. (DX12 at 338-39.)[14]

Since 1974, the FDA has approved the use of simethicone in combination with other pharmaceuticals. (PTX75 at MC97921.) By the time of Dr. Garwin's claimed invention, simethicone was a well-known and increasingly popular antiflatulent, sold commercially in more than twenty-five products such as Gas-X (R) and Mylanta (R) . (DX87-2.)

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including a study by Drs. Alfred Rider and Hugo Moeller, found that simethicone treated intestinal gas and bloating in 75.5 percent of the 200 patients studied. (DX103-1.) Although McNeil later provided the PTO with numerous articles tending to show the effectiveness of simethicone, these articles were not submitted until after the '505 patent had issued. (DX13 at 123-70.)

[14] At the time of the claimed invention, bismuth subsalicyclate was sold as Pepto-Bismol (R), and attapulgite was an ingredient in the tablet form of Kaopectate (R) . (DX12 at 338-39.)

The dosage regimen in the Garwin patents was not new. Other marketed OTC products contained 125 milligrams of simethicone. (DX87.) The amounts specified for loperamide in the Garwin patents were those already used in other OTC products, including Imodium A-D (DX87-2 at PER7645, 7648.)

2. Specific References

At least as early as 1980, an Australian pharmaceutical reference publication, the *MIMS Annual* ("MIMS reference"), included a reference to a product called "Diareze." (DX80.) One form of Diareze combined the antidiarrheal attapulgite with simethicone. (DX80 at PER3290.) In describing Diareze, the MIMS reference states: "Simethicone in the suspensions helps relieve the pain and discomfort of gaseous distention. . . ." (*Id.*)[15]

Second, the Chavkin patent covered, *inter alia*, the combination of polycarbophil and simethicone. (Levitt at TT 727; DX83.) Polycarbophil was a well-known antidiarrheal at the time of Dr. Garwin's alleged invention. (DX12 at 338-39.) Third, French Patent Publication 2,565,107 taught the use of activated charcoal and dimethicone. (Levitt TT at 725; DX81 at PER239.) Dimethicone is another name for simethicone. (DX132.) Before Dr. Garwin's alleged invention, activated charcoal had been used as an antidiarrheal. (Levitt TT at 595.)

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[15] McNeil did not present the 1980 edition of the MIMS Reference during the prosecution of either the '505 patent or '054 patent. (PTX5, 6.)

4. Differences Between the Claimed Invention and the Prior Art

Although the concept of combining an antidiarrheal with simethicone was not new to Dr. Garwin, the prior art does not disclose the exact combination at issue in this case. That is, the Garwin claims in suit combine simethicone with loperamide rather than attapulgite, activated charcoal, or polycarbophil. (Levitt TT at 606-08.)[16]

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[16] McNeil attempts to draw a distinction between the Garwin patents and the prior art references based on the fact that the prior art involves absorbent and adsorbent antidiarrheals, instead of an opiate-type antidiarrheal, like loperamide. On the one hand, absorbent and adsorbent materials take up and remove some of the toxins and bacteria present in the intestinal tract. Absorbent materials also solidify the intestinal contents by absorbing excess water. Loperamide, on the other hand, acts locally in the intestine to: (1) regulate muscular contractions of the intestinal tract; (2) limit the excess amount of secretions made by the intestinal tract as a reaction to toxins in a diarrheal state; (3) increase absorption of water across the intestinal muscosa so that the water can be reabsorbed into the body; and (4) increase anal sphincter pressure, thus treating the patient's fecal incontinence. (Garwin TT at 108-122.) Attapulgite had been found to be comparable in efficacy to loperamide. (DX157 at 37.) McNeil's argument, however, sets up a distinction without a meaningful difference. Significantly, Dr. William Snape, one of McNeil's expert witnesses, offered no explanation regarding why a difference in the mode of operation of an opiate-type antidiarrheal as compared to an absorbent/adsorbent-type antidiarrheal would deter one of ordinary skill in the art from combining loperamide with simethicone. (Snape TT at 1218-20.)

5. Date of Invention and Requisite Level of Skill in the Art

The parties have agreed that "the Garwin '054 and '505 patents relate to the field of identifying combinations of active ingredients for commercial medications for symptoms of diarrhea in conjunction with one or more additional gastrointestinal symptoms." (DX571, McNeil's Resp. to Interrog. 6.)

The date of Dr. Garwin's alleged invention is November 1, 1989, the filing date of the patent application.[17] At that time:

> One of ordinary skill in the art of the Garwin '054 and '505 patents would have been a medical doctor with pharmaceutical or clinical research experience, or a

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[17] Priority of invention "goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice." *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993). While Dr. Garwin's notebook includes a memorandum of September 23, 1988 documenting his conception of combining loperamide and simethicone in a single composition to treat diarrhea and gas, at trial McNeil failed to produce any evidence of diligence in reducing the alleged invention to practice. However, because McNeil has not established when the claimed invention was actually reduced to practice, the filing date of the first Garwin patent application serves as the date of constructive reduction to practice. *See Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998). In light of this date of invention, the Chavkin patent is prior art.

> chemist, biochemist, or pharmacologist with a doctoral degree and with experience in the pharmaceutical industry, and either of which would also have had ability in identifying appropriate and acceptable combinations of active ingredients for commercial medications for symptoms of diarrhea in conjunction with one or more additional gastrointestinal symptoms.

(DX571, McNeil's Resp. to Interrog. 7).

In addition, one of ordinary skill in the art would have known that loperamide was a commercially successful prescription antidiarrheal. (Levitt TT at 595-96.)

6. Motivation to Combine

To counter the powerful attraction of a hindsight-based obviousness analysis, the case law makes clear that Perrigo must show that there was some motivation, suggestion, or teaching of the desirability of making the specific combination at issue. *See, e.g., In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). In this case, there was abundant motivation to combine loperamide with simethicone. As Dr. Levitt testified:

> [At the time of Dr. Garwin's claimed invention] you want to make a combination that treats diarrhea and gas. The concept is out there. The question is what products are you going to use, and you're very likely to use, obvious to use, the best-selling antidiarrheal in the United States and combine it with essentially the only compound you can combine it with, which is simethicone, which is the one compound that is

approved as efficacious for gas problems in the United States.

(Levitt TT at 670.)[18] Put differently, the prior art, especially the teachings of those references that disclosed the concurrence of diarrhea and flatulence (e.g., the Gorbach reference) together with those references that combined antidiarrheals with simethicone (the Chavkin patent, French patent, and the MIMS reference) would have clearly

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[18] McNeil argues that the fact that no one had written about combining loperamide with simethicone suggests the absence of a motivation to combine the two. This argument assumes that others were not disinclined to write about such a combination because of the sheer obviousness of that combination. McNeil also contends that the fact that certain antidiarrheals, particularly bismuth subsalicyclate, had not been combined with simethicone suggests the nonobviousness of the Garwin patents. There is a plausible medical explanation, however, for why bismuth subsalicyclate was not combined with simethicone; there is evidence that bismuth subsalicyclate itself was understood to act as an antiflatulent. (Snape TT at 1207-08.) Furthermore, McNeil advances the argument that the lack of evidence regarding whether simethicone reduced intestinal gas would deter one of ordinary skill in the art from considering the loperamide-simethicone combination; this argument is unconvincing for two reasons. First, this argument ignores the fact that three other antidiarrheals had previously been combined with simethicone for the treatment diarrhea and flatulence. Second, this contention is inconsistent with McNeil's statement to the PTO that it did "not disagree that simethicone is a known composition for the treatment of flatulence. . . ." (DX12 at 40.)

suggested this combination to one of ordinary skill in the art. (Levitt TT at 605-07.)[19]

7. Secondary Considerations

The so-called "secondary considerations" are part of the obviousness analysis. Secondary considerations, which relate to objective evidence of nonobviousness, include evidence of commercial success, unexpected results, and copying of the claimed invention.

1. Imodium Advanced in the Marketplace

Evidence of commercial success is a secondary consideration. With the FDA's approval, McNeil began selling Imodium Advanced in 1997. (Eble TT at 75; McDonagh TT at 181.) Around the same time, McNeil launched a massive $ 45 million marketing and advertising campaign. (DX67, 135.) McNeil described its marketing plan for Imodium Advanced's introduction in a sales publication: "With this heavy media-spending plan, Imodium will significantly out-spend all other competitors and remain the category share-of-voice leader." (DX67 at MC36404.)

In 1997, sales of Imodium Advanced neared $ 10 million, and approached $ 27.7 million in 1998, the product's first full year of sales. (McDonagh TT at 181-82; Wang Goodrich TT at 233, 236; PTX57.) After an initial period of rapidly

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[19] In view of the fact that the basic loperamide patent was nearing expiration, to a McNeil researcher, the motivation to combine loperamide with simethicone would have been overwhelming.

gaining market share, the rate of Imodium Advanced's sales' increases slowed. (PTX57.)[20] Moreover, McNeil's Imodium A-D product, which contains loperamide without simethicone, remains on the market. (PTX57, 465.) As McNeil recognizes, sales of Imodium Advanced products have come at the expense of sales of Imodium A-D. (Wang Goodrich TT at 274; PTX57.) For the years 1998 through 2001, sales of Imodium Advanced chewable tablets were relatively flat. (PTX57.)[21] In addition, the total amount of sales of Imodium Advanced chewable tablets and Imodium A-D products has also been relatively flat over the same period. (*Id.*)

2. McNeil's Clinical Studies, Unexpected Results, and Synergy

In light of Dr. Garwin's proposal to combine loperamide and simethicone, McNeil proceeded with an initial clinical study of the combination's safety and efficacy. Based on the study's results, McNeil decided to pursue further studies. (PTX123 at MC16631.) Thereafter McNeil conducted three additional clinical studies of a single tablet combining loperamide with simethicone. That tablet was compared to

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[20] McNeil's projections indicate that the total sales of all Imodium Advanced products will approach $ 200 million by the end of 2002. (PTX57, 455 at MC100885).

[21] In 2001, McNeil began selling an Imodium Advanced caplet. (Wang Goodrich TT at 229.) The total amount of sales of all of McNeil's Imodium products - including sales of the caplet - increased in 2001. (PTX57.) It is noteworthy that this sales increase corresponds with an increase in advertising expenditures. (PTX464.)

loperamide alone, simethicone alone, and a placebo. (PTX123 at MC16631; PTX111, 114, 118.) Some of these studies' findings were submitted to the FDA. (PTX63 at PER3501.)

Evidence of unexpected results or synergy may be introduced to a show a claimed invention's nonobviousness. McNeil contends that the combination claimed in the Garwin patents provides unexpectedly enhanced diarrhea relief, including faster relief in the critical first twelve hours, and that the claimed combination also provides unexpectedly enhanced gas relief. In addition, McNeil argues that these clinical studies demonstrate the existence of synergy for the combination drug during the first twelve hours after the initial dose. These contentions are supported by statistical analysis. (Thibodeau TT at 517-19, 526; Kuskowski TT at 767, 773-74; PTX491 at 2, 4, 6; DX676.)[22]

Nonetheless, there are problems with the underlying studies that significantly limit their probative value. First, the results of the individual studies were inconsistent and not readily reproducible. (Levitt TT at 652-53.) Second, McNeil's studies compare only the loperamide-simethicone combination to its components individually and to a placebo, and not to a combination of simethicone and another antidiarrheal. (PTX111, 114, 188, 123 at MC16631.) Third, the studies measured gas relief based solely on subjective criteria such as "mild," "moderate," "moderately severe," and "severe." (PTX111 at MC13741; Kaplan TT at 332-33.) Fourth, it is

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[22] After its claims had been twice rejected for obviousness, as predicted by Judge Learned Hand, McNeil returned to the PTO to argue that unexpected results proved that the Garwin patents were nonobviousness.

not clear that it is proper to combine all four studies for the purposes of statistical analysis. (Thibodeau TT at 528-30.)

Moreover, in assessing McNeil's evidence of unexpected results, it is significant that as a self-limiting disease, diarrhea "goes away on its own, without any treatment." (Kaplan TT at 311.) Within forty-eight hours of its onset, diarrhea "tends to go away." (Thibodeau TT at 547). Thus, the amelioration of symptoms may be due to pharmaceutical treatment or the mere passage of time. Among other things, this fact counsels against accepting McNeil's sweeping assertions that the clinical studies show unexpected results and synergy that are not merely statistically significant, but biologically and medically significant as well.

In view of these problems with the studies and when considering the data as a whole, they largely confirm what one would expect, namely that loperamide is good for treating diarrhea and contributing to the relief of abdominal discomfort, and that simethicone contributes to the relief of abdominal discomfort. (Levitt TT at 621-22, 648.)

3. Copying

Evidence that others have copied the claimed invention is objective evidence of nonobviousness. However, Perrigo did not copy the claimed invention. (Needham TT at 807, 828.)[23]

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[23] To the extent that a generic drug manufacturer's attempt to create the bioequivalent of a pioneer manufacturer's drug, without more, may be considered copying, I note that a showing of copying is only equivocal evidence of nonobviousness. *See Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000)(*citing*

In developing its ANDA product, Perrigo tested a number of different formulations over several years. (PTX10 at 1757-2031.)

3. STEVENS PATENTS

1. Claims at Issue

Like the Garwin patents, the Stevens patents disclose a drug combining loperamide and simethicone. The Stevens patents add an impermeable polymeric barrier separating the simethicone from the loperamide. (PTX3, col. 12 line 54 - col. 14, line 3; PTX4, col. 12 line 60 - col. 14, line 22.) It is theorized that simethicone migrates over time and surrounds the loperamide, hindering its dissolution; by attempting to prevent this migration, the Stevens patents are aimed at an "extended shelf life" and "improved stability." (PTX3, '376 patent, col. 3, line 50-57; col. 12, line 48.) The following claims in the Stevens patents are at issue:

Claims 1 and 2 of the '376 Patent

> **1.** A solid oral dosage form for the treatment of gastrointestinal distress comprising a therapeutically effective amount of a pharmaceutical for the treatment of gastric disorders selected from the group consisting of diphenoxylate, loperamide, loperamide-N-oxide, pharmaceutically acceptable salts thereof, and combinations thereof; and

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In re GPAC, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

A therapeutically effective amount of simethicone wherein the oral dosage form has a first portion containing the pharmaceutical and a second portion containing simethicone and the first and second portions are separated by a pharmaceutically acceptable polymeric barrier, which is impermeable to simethicone and the pharmaceutical.

2. The solid dosage form of claim **1** wherein the pharmaceutical comprises loperamide Hcl.

Claim 1,2 and 3 of the '641 Patent

1. A method of enhancing the dissolution profile of a pharmaceutical from a solid dosage form comprising the pharmaceutical and simethicone, comprising:

providing the pharmaceutical in a first portion of said dosage form, said pharmaceutical is selected from the group consisting of diphenoxylate, loperamide and loperamide-N-oxide, pharmaceutically acceptable salts thereof, and combinations thereof;

providing the simethicone in a second portion of said dosage form; and separating said first and second portions with a pharmaceutically acceptable polymeric barrier which is impermeable to simethicone and the pharmaceutical.

2. The method of claim **1** wherein the pharmaceutical is selected from the group consisting

of loperamide, loperamide-N-oxide, pharmaceutically acceptable salts thereof and combinations thereof.

3. The method of claim **1** wherein the pharmaceutical contains loperamide HCl.

Pursuant to *Markman*, I previously construed disputed claim terms. Specifically, the term "portion" was construed as "a part of the whole"; the term "polymeric barrier" was construed as "a material that is a polymer or contains polymers and which separates the first portion from the second portion"; and the term "impermeable to simethicone and the pharmaceutical" was interpreted as meaning "not permeable, impassable to simethicone and the pharmaceutical."

B. Perrigo's ANDA Product

Perrigo employs a four-step process to make its ANDA product, which is a bilayer tablet. In the first step, the loperamide is formulated into granules. (Schwartz TT at 402; PTX14 at PER930-43; PTX490 at PER10102-10119.)[24] In making the granules, Perrigo agglomerates two milligrams per tablet of loperamide with 148 milligrams per tablet of other materials, namely dextrates, sodium starch glycolate, microcrystalline cellulose, pre-gelatinized starch, and water. During the granulation process, the starch acts as an adhesive, causing the various particles to stick together. (Celik TT at

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[24] The polymeric materials Perrigo uses in its tablet are disclosed in the Stevens patents only as excipients, with no statement that they could function as impermeable barrier materials or as impermeable polymer coatings. (PTX3, 4.)

883-87; Schwartz TT at 405-410.) These granules are blended with various inactive ingredients, making a loperamide layer mix. (PTX14 at PER934; Schwartz TT at 405-06; Danielson Dep. I at 93:10-17.) Next, Perrigo blends simethicone powder with inactive ingredients to make a simethicone layer mix. (Schwartz TT at 402; PTX14 at PER936-40; DX146.) Finally, Perrigo compresses these layers to form a bilayer tablet. (Schwartz TT at 402; PTX14 at 937, 941; DX146.)

C. Impermeable Polymeric Barrier[25]

The Stevens patents disclose tablets employing a polymeric barrier that is impermeable to loperamide and simethicone, separating the loperamide in a first portion of the tablet from the simethicone in a second portion. More specifically, the barrier materials disclosed in the Stevens patents form films having smooth surfaces which are not permeable to liquids in general, or simethicone in particular. (DX583, 665, 666.) With respect to the infringement of the Stevens patents, the parties essentially agree that this dispute turns solely on whether the Perrigo's ANDA product employs

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[25] Perrigo has taken the position that certain materials used in its ANDA drug are not polymeric, and, on this basis, the Stevens patents are not infringed. At trial, both parties presented evidence related to whether certain materials should be considered "polymeric." At bottom, this dispute raises the question - primarily of interest to a semanticist - of whether "monomeric" and "polymeric" are mutually exclusive terms. In light of my construction of "polymeric" as "a material that is a polymer or contains polymers," Perrigo's product does contain polymeric materials.

an impermeable polymeric barrier. (Pl.'s Post-Trial Br. at 46.)

Simply, Perrigo's product does not contain an impermeable barrier. Rather than being buried in the granules, as McNeil contends, loperamide particles in Perrigo's ANDA product are exposed on the surface of the granules. (Celik TT at 888-901; DX638.) Additionally, in at least three different ways, Perrigo's granules have been readily shown to be permeable. First, mercury porosity tests show that Perrigo's granules are highly permeable. (Celik TT at 897-99; DX670.) Second, the mercury porosity tests confirm that the loperamide granules have relatively large openings through which simethicone can pass. (Celik TT at 900; DX666.) Third, Perrigo's granules tend to wick, or soak up the simethicone. (Celik TT at 901-02; DX31 at MC6681.) That is, Perrigo's granules in fact absorb simethicone.[26]

McNeil takes the position that Perrigo's granules are impermeable because Perrigo's ANDA product shows a good dissolution profile with respect to loperamide. (Schwartz TT at 475.) This arguments fails, however, because it is inconsistent with the Court's *Markman* ruling, in which I rejected McNeil's proposed construction of impermeability that referred to the rate of dissolution of the loperamide. Additionally, the testimony of McNeil's witnesses belies the

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[26] Perrigo's evidence that its tablet absorbs simethicone is supported by a statement made by McNeil. In an report not prepared for the purposes of this litigation, McNeil's expert described dextrates, one of the principal ingredients in Perrigo's ANDA product, as "providing absorptive capacity for simethicone oil. . . . ." (DX31 at MC6681.)

contention that impermeability is determined with respect to the rate of dissolution. In particular, Dr. Joseph Schwartz has conceded that good dissolution results can be obtained without infringing the Stevens patents. (Schwartz TT at 480.)

C. Obviousness of Stevens Patents

1. Date of Invention and Requisite Level of Skill in the Art

For present purposes, the date of invention is the filing date of the Stevens patents, May 21, 1992. Like the Garwin patents, the Stevens patents relate to the field of formulating commercial combination patents. (DX571; McNeil's Resp. to Interrog. 6.) Similarly, at the time of the claimed invention one of ordinary skill in the art was a person having a doctorate degree in pharmaceutics or chemistry, and practical experience in the field of formulating commercial combination medications. (DX571; McNeil's Resp. to Interrog. 7.)

2. Scope and Content of the Prior Art

1. Garwin Patents

The Garwin patents, in Examples I and II, teach the separation of loperamide from simethicone by putting the two into separate tablet layers. (PTX1, 2.) In these examples, the loperamide and the simethicone are separated by placing the two compounds in distinct layers.

b. Rider and Valentine Patents

United States Patent 4,198,390 ("the Rider patent") teaches that simethicone is at least temporarily deactivated when combined with antacids. (DX61.)[27] More importantly, the Rider patent teaches that due to the problem of the antacid ingredients deactivating the simethicone one should use a barrier between the antacid and the simethicone. (*Id.* at col. 2, lines 38-44; col. 5, lines 11-12.)[28] In addition, United States Patent 5,073,384 ("the Valentine patent") teaches that simethicone migration is prevented when the simethicone is adsorbed onto maltodextrin. (DX90.)[29]

3. Differences Between the Claimed Invention and the Prior Art

The Garwin patents teach the separation of loperamide and simethicone into two separate layers, whereas the Stevens patents add an impermeable polymeric barrier between the two layers. The Rider patent separates simethicone from an antacid by employing an impermeable polymeric barrier.

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[27] The figures included in the Stevens patents are identical to those in the earlier Rider patent.

[28] French Patent Publication 2,565,107, discussed above in connection with the Garwin patents, teaches an additional configuration, namely an onion-like layering system, for separating simethicone from an antidiarrheal attapulgite. (DX132.)

[29] Significantly, Perrigo's ANDA product also employs the mechanism of adsorbtion to prevent simethicone migration.

4. Motivation to Combine

The pertinent prior art references suggest to one of ordinary skill in the art that the loperamide should be in one layer of the tablet and the simethicone in the other, with an impermeable polymeric barrier between the two. Specifically, the Garwin patents provide the motivation to separate loperamide into one layer of a bilayer tablet, and simethicone into the other. Furthermore, the Rider patent motivates an artisan to include an impermeable polymeric barrier in order to prevent the simethicone from migrating from one layer to an adjacent pharmaceutical-containing layer. (DX61, col. 2, lines 38-44, col. 5, lines 11-12.)[30]

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[30] McNeil takes the position that the motivation to combine is absent because the prior art failed to indicate that simethicone effected the dissolution of the loperamide. However, one of McNeil's experts, Dr. Schwartz, admitted at trial that the Rider patent and Stevens patents are directed at solving the same problem:

> Q: What do the Stevens' patents have to say about [the simethicone migration problem]?
>
> A: Well, their invention prevents the simethicone from migrating into the pharmaceutical.
>
> . . .
>
> Q: You would accept agree with me that Ryder [sic] discloses an invention for preventing simethicone from migrating into the pharmaceutical?
>
> A: I'll accept that.

CONCLUSIONS OF LAW

5. HATCH-WAXMAN ACT

It is significant that the parties in this action are a drug manufacturer and its generic competitor. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § § 355, 360cc, and 35 U.S.C. § § 156, 271 (the "Hatch-Waxman Act), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs, and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. Pursuant to the Hatch-Waxman Act, a manufacturer that seeks to market a generic drug may submit an ANDA for approval by the FDA, rather than submitting a full New Drug Application ("NDA") concerning the safety and efficacy of the generic drug. Likewise, the generic manufacturer may rely on safety and efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product. *See* 21 U.S.C. § 355(j)(2)(A). *See generally Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed Cir. 2002).

Here, as the holder of an approved NDA for a chewable loperamide and simethicone tablet, McNeil enjoys a period of exclusivity for its combination product without regard to the

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Put differently, Dr. Schwartz considered the Stevens patents and Rider patent as disclosing the same "invention," namely the prevention of simethicone migration into the pharmaceutical.

protection, if any, afforded by the patent laws. If the patent-holder files suit, the FDA will not approve a generic for marketing under an ANDA until the patent has expired, thirty months have passed since the patentee received notice of the ANDA, or the suit is resolved. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1552 (Fed. Cir. 1996).

II. INVALIDITY OF GARWIN PATENTS

With respect to the earlier Garwin patents, Perrigo concedes that its ANDA product literally infringes claims 14 and 16 of the '505 patent, and claim 15 of the '054 patent, if they are valid. *See* 35 U.S.C. § 271(e)(2)(defining submission of ANDA as act of infringement). Therefore, the issue with respect to the Garwin patents is whether those patents are invalid as obvious.[31]

1. Legal Standard for Obviousness

1. Presumption of Validity

Patents are presumed valid, and the law requires Perrigo, as the patent challenger, to prove invalidity by clear and convincing evidence. *See, e.g., Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1367 (Fed Cir. 2002). Having conceded infringement, Perrigo must clear

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[31] In its Answer and Counterclaims, Perrigo pled defenses under 35 U.S.C. § § 102 and 112. However, Perrigo failed to raise this defense in its claim-by-claim defenses or at trial. At trial, Perrigo's only defense to its admitted infringement of the Garwin patents was that the asserted claims are invalid for obviousness under 35 U.S.C. § 103.

this high hurdle in order to prove the invalidity of the Garwin patents.

2. Factors Related to Obviousness

Perrigo argues that claims of the Garwin patents at issue are invalid as obvious. A patent is invalid for obviousness:

> If the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103. "Although it is well settled that the ultimate determination of obviousness is a question of law, it is also well understood that there are factual issues underlying the ultimate obviousness decision." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1349 (Fed. Cir. 2001) (*citing Richardson-Vicks*, 122 F.3d at 1479.) Specifically, the obviousness analysis is based on four underlying factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). "'[A] reasonable expectation of success, not absolute predictability' supports a conclusion of obviousness." *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1343 (Fed. Cir. 2000)(*quoting In re Longi*, 759 F.2d 887, 896 (Fed. Cir. 1985).

2. Analysis of the Garwin Patents

1. Motivation to Combine

"In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention." *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001). Furthermore, "[the] case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). This evidence may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996). Here, filtered through the knowledge of one skilled in the art, the prior art disclosed that flatulence is frequently a concurrent symptom of diarrhea, and that this problem can be addressed by combining a known antidiarrheal with simethicone. In addition, by the time of Dr. Garwin's claimed invention, loperamide was a well-known and successful antidiarrheal. Accordingly, there was a clear motivation to combine the loperamide and simethicone.

2. Perrigo's Prima Facie Case of Obviousness

Considering the date of invention and level of ordinary skill in the art, the scope and content of the prior art, the

differences between the accused product and prior art, and the motivation to combine, Perrigo has made out a strong prima facie case of obviousness.

3. Secondary Considerations

A prima facie case of obviousness may be rebutted by secondary considerations. *See, e.g., In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). Indeed, the secondary considerations "may often be the most probative and cogent evidence in the record" related to the issue of obviousness. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). "Secondary considerations, when present, must be considered in determining obviousness." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000). In this case, McNeil has advanced a number of arguments in an effort to rebut Perrigo's strong prima facie case of obviousness. These efforts, however, are unavailing.

1. Unexpected Results

The Federal Circuit has made clear that evidence of unexpected results may provide important evidence that a claimed invention should not deemed obvious:

> One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of "unexpected results," i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward -- that which would have been

> surprising to a person of ordinary skill in a particular art would not have been obvious.

In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995). To show unexpected properties, McNeil must show enhancement in "one of a spectrum of common properties" when that enhancement would not have been expected by one of skill in the art. *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987). Here, although McNeil has presented evidence tending to show enhancement, there are compelling reasons to question the validity of the underlying clinical studies upon which that evidence is based, and McNeil's proposition that such evidence was unexpected is doubtful. The results of McNeil's clinical studies are also of limited relevance because they do not compare the loperamide-simethicone with the closest prior art, i.e., another antidiarrheal and simethicone. *See In re Baxter Travenol Labs*, 952 F.2d 388, 392 (Fed. Cir. 1991).

2. Commercial Success

Sales of the Imodium Advanced tablet have been substantial, and the marketed product is the product disclosed in the Garwin patents. *See Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)("[A] prima facie case of nexus is generally made out when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." Nevertheless, the probative value of the commercial success of Imodium Advanced is significantly mitigated by the fact that Imodium Advanced's sales are the

calculated result of an aggressive marketing campaign of unprecedented scope in the antidiarrheal market.[32]

c. Conclusion

Given the strong prima facie case of obviousness, including the clear motivation to combine, and the limitations and defects in the secondary evidence presented by McNeil, Perrigo has proven by clear and convincing evidence that claims 14 and 16 of the '505 patent and claim 15 of the '054 patent are invalid for obviousness. *See Richardson-Vicks*, 122 F.3d at 1483-84.

3. NONINFRINGEMENT OF STEVENS PATENTS

1. Literal Infringement Analysis

After determining the meaning and scope of the asserted patent claims pursuant to *Markman*, an infringement analysis entails a determination of whether the accused product or method meets each and every limitation of the properly construed claim. *See, e.g., Tate Access Floors, Inc. v. Macess*

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[32] McNeil's marketing expenditures appear to be consistent with an overall strategy for stymieing generic competition. By heavily promoting the combination product, McNeil can in effect transfer sales from the non-patent-protected loperamide product to its combination drug. Regardless of whether the combination drug ultimately gains patent protection, this combination drug enjoys a significant period of exclusivity pursuant to the Hatch-Waxman Act. Moreover, because loperamide is sold in generic form, McNeil benefits from the transference of sales from the loperamide-alone product to its combination drug.

Techs., Inc., 222 F.3d 958, 964 (Fed. Cir. 2000). *See also Bai v. L & L Wings*, 160 F.3d 1350, 1353 (Fed. Cir. 1998)(determination of infringement is question of fact). For the reasons set forth in the findings of fact, Perrigo does not literally infringe the asserted claims of the Stevens patents.

B. Infringement Under the Doctrine of Equivalents

If a claim element is not literally infringed, infringement may be found under the doctrine of equivalents if the accused product or method contains the equivalent of that claim element. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 137 L. Ed. 2d 146, 117 S. Ct. 1040 (1997). As the law stood at the time of trial, when an amendment narrows the scope of a claim for a reason related to the statutory requirements for patentability, prosecution history estoppel acts as a complete bar to the application of the doctrine of equivalents to the amended claim element. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed Cir. 2000), *vacated by* 535 U.S. ___, No. 00-1543, 2002 U.S. LEXIS 3818 (May 28, 2002). McNeil admits that elements of the asserted claims of the Stevens patents were amended during prosecution for reasons related to patentability.

After the trial in this case had concluded, the United States Supreme Court decided *Festo*. In rejecting the Federal Circuit's complete bar rule, the Supreme Court concluded that although prosecution history estoppel can bar challenges to a wide range of equivalents, its reach requires an examination of the subject matter surrendered by the narrowing amendment:

> There are some cases . . . where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

Id. at *33-34. On the record before me, McNeil has not presented any evidence rebutting the presumption that prosecution history estoppel bars McNeil from claiming infringement under the doctrine of equivalents. Furthermore, Perrigo has proven the invalidity of the Stevens patents; therefore, I need not reach the issue of infringement under the doctrine of equivalents.

4. INVALIDITY OF STEVENS PATENTS

Given the strong prima facie case of obviousness and the minimal secondary evidence presented by McNeil, Perrigo has proven by clear and convincing evidence that claims 1 and 2 of the '376 patent and claims 1 through 3 of the '641 patent are invalid for obviousness.[33]

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[33] Because I have found that the Stevens patents are not infringed, I need not reach Perrigo's alternative arguments that the Stevens claim lack definiteness and fail to distinctly claim the invention. (Def. Post-Trial Br. at 75.) Furthermore, having found

5. ATTORNEYS' FEES

An award of attorneys' fees to the prevailing party is authorized in an "exceptional" case. *See* 35 U.S.C. § 285. In assessing whether a case qualifies as exceptional, I must consider the totality of the circumstances. *See Kaufman Co., Inc. v. Lantech, Inc.*, 807 F.2d 970, 978-79 (Fed Cir. 1986). As the party seeking attorneys' fees, Perrigo must prove the exceptional nature of the case by clear and convincing evidence. *See Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 810-11 (Fed. Cir. 1990). Exceptional cases are normally those involving bad faith litigation or misconduct by the patentee in procuring the patent. *See Cambridge Prods., Ltd. v. Penn Nutrients, Inc.*, 962 F.2d 1048, 1050-51 (Fed. Cir. 1992). Particularly during the prosecution of the patents in suit, McNeil's conduct was careless, irresponsible, and, at the very least, tantamount to studied and deceptive ignorance. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1384 (Fed. Cir. 2001). McNeil's repeated erroneous representations, failure to disclose relevant prior art, and overall persistence in prosecuting exceedingly obvious "inventions" make this case exceptional.

Although McNeil's misconduct during prosecution alone makes this case exceptional, there is further evidence warranting an award of attorneys' fees. It is significant that McNeil is a highly sophisticated party, readily capable of assessing not only the merits of its claimed invention, but also

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that the Stevens patents are invalid for obviousness, I need not reach the host of other arguments Perrigo advances in support of its position that the Stevens patents are invalid. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed. Cir. 1999).

its expected profits as compared to the costs that would be incurred in the event that their patents were held invalid. Put differently, the Garwin and Stevens patents amount to a scheme for extending the life of a drug about to go off patent, and McNeil executed this scheme without the slightest regard for the intent and purposes of the patent laws. Indeed, McNeil's sole motive was to compromise these statutes and constitutional protections for the sake of profits.

CONCLUSION

The patent laws "promote the Progress of Science and useful Arts" by rewarding innovation with a temporary right to exclusivity. U.S. CONST., art. I, § 8, cl. 8. *See also Festo*, 152 L. Ed. 2d 944, 2002 U.S. LEXIS 3818, 122 S. Ct. 1831 at *16.[34] Long ago, in *Hotchkiss v. Greenwood*, 52 U.S.

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[34] As early as 1813 Thomas Jefferson, the first administrator of the United States Patent Office, memorialized in writing his critical view of the excessive issuance of patents. "Instead of refusing a patent in the first instance, as the board was authorized to do, the patent now issues of course, subject to be declared void on such principles as should be established by the courts of law." 13 THE WRITINGS OF THOMAS JEFFERSON 336 (A. Bergh ed. 1907). Jefferson explained the reasons for these objections with eloquence that continues to resonate:

> [The idea's] peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and

248, 11 How. 248, 267, 13 L. Ed. 683 (1851), the Supreme Court established that the sine qua non of patentability is invention, and as stated in 35 U.S.C. § 100(a), the legal definition of invention is synonymous with discovery. As is widely understood, a discovery is an act of "gaining knowledge of or ascertaining the existence of something previously unknown or unrecognized." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 647 (1993). Over time, patent law has developed its own, new language, and has even come to require special qualifications for lawyers appearing before the PTO. These developments tend to obscure the fundamental notions of invention and discovery.

Acting within this often esoteric area of the law, patent lawyers are called upon to play the roles of chemists, engineers, physicians, and physicists - now, they are also asked to be magicians. That is, patent lawyers are asked to defend - with smoke and incantations when necessary - business-driven decisions having nothing to do with inventing or discovering anything. Consistent with schemes to prolong the legally-protected period of exclusivity, companies hire highly talented attorneys to perform acts of legal legerdemain in order to make modest developments look and feel like inventions, when in reality the purported discovery is nothing more than a creation of an advertising and marketing department. In-house counsel should be cautioned that complicity in patent prosecution for unsanctioned legal

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> improvement of his condition, seems to have been peculiarly and benevolently designed by nature when she made them, like fire, expansible over all space . . .

Id. at 333-34.

purposes may give rise in the future to review of that behavior by the appropriate attorney disciplinary machinery. Advancing a client's economic interests is not a license to forget one's ethical responsibilities.

It is not lost on this Court that by developing ("not inventing") a combination drug, the law automatically permitted McNeil a three-year period of exclusivity, which ran from October 1997 to October 2000. However, by concocting multiple patent applications and litigating their validity, this period of exclusivity has been extended by two years and, with an appeal, will extend even further, effectively doubling the initial period of exclusivity. The business-driven decision that it is worth the investment to "invent an invention" will continue unabated unless a vigorous PTO or a Court sees this transparent attempt to subvert the patent laws for what it is. The patent laws are not the private sandbox of pharmaceutical companies. Regrettably, I am constrained by law to award only counsel fees for Plaintiff's behavior, although I am not unmindful of the fact that while this patent litigation continues, competition in the marketplace is foreclosed and the public is forced to pay higher prices.

While the trial attorneys in this case have proven themselves informed, articulate, and instructive, in the end I was left to dispel the illusions concealing the true nature of the "invention" to reach my own conclusion: as Gertrude Stein phrased it, "there is no there there."

An appropriate Order follows.

ORDER

AND NOW, this day of June, 2002, upon consideration of the parties' Proposed Findings of Fact and Conclusions of Law and Post-Trial Briefs, Plaintiff's Motion to Strike New Affirmative Defenses and Counterclaims, Defendants' Motion for Attorney's Fees, and the record and the applicable law, and for the foregoing reasons, it is hereby **ORDERED** that:

1. Plaintiff's Motion to Strike New Affirmative Defenses and Counterclaims (Document No. 90) is **DENIED** as moot.

2. Defendants' Motion for Attorney's Fees (Document No. 101) is **GRANTED**.

3. It is **DECLARED** that claims 14 and 16 of United States Patent 5,248,505 are invalid, and judgment is **ENTERED** in favor of Defendants and against Plaintiff on Plaintiff's claim for infringement of United States Patent 5,248,505.

4. It is **DECLARED** that claim 15 of United States Patent 5,612,054 is invalid, and judgment is **ENTERED** in favor of Defendants and against Plaintiff on Plaintiff's claim for infringement of United States Patent 5,612,054.

5. Judgment is **ENTERED** in favor of Defendants and against Plaintiff on Plaintiff's claim for literal infringement of United States Patent 5,679,376.

6. Judgment is **ENTERED** in favor of Defendants and against Plaintiff on Plaintiff's claim for literal infringement of United States Patent 5,716,641.

7. It is **DECLARED** that claims 1 and 2 of United States Patent 5,679,376 are invalid.

8. It is **DECLARED** that claims 1, 2, and 3 of United States Patent 5,716,641 are invalid.

9. Defendants shall submit a petition for counsel fees by July 10, 2002. Plaintiff shall have until July 29, 2002 to file a response.

BY THE COURT:

Berle M. Schiller, J.